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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/679,852	10/05/2000	Kendall J. Blumer	23102.0001U2	9176

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ATLANTA, GA 30303-1811

EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 01/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/679,852

Applicant(s)

BLUMER, KENDALL J.

Examiner

Robert Landsman

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 21-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 27-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____

DETAILED ACTION

1. Formal Matters

- A. Amendment A, filed 11/13/02, has been entered into the record. Claims 1-26 are pending in the application. However, claims 21-26 have been withdrawn as being drawn to a non-elected invention. In Amendment A, Applicants added new claims 27-30. Therefore, claims 1-30 are pending and claims 1-20 and 27-30 are the subject of this Office Action.
- B. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Title

- A. The objection to the title has been withdrawn in view of Applicants' amendment.

3. Figures

- A. The objection to the Brief Description of the Figures regarding Figures 3 and 4 has been withdrawn in view of Applicant's amendments to the specification and Figures.

4. References

- A. The objection to the specification regarding missing references 8 and 10 has been withdrawn in view of Applicant's addition of these citations to the "References" section of the disclosure.

5. Claim Rejections - 35 USC § 112, first paragraph – enablement

- A. All rejections under 35 USC 112, first paragraph, as recited on pages 3-6 of the Office Action dated 5/8/02 have been withdrawn in view of Applicant's explanation of the claimed methods and the use of the terminology in these methods.

6. Claim Rejections - 35 USC § 112, second paragraph

- A. All rejections under 35 USC 112, second paragraph, as recited on pages 6-9 of the Office Action dated 5/8/02 have been withdrawn in view of Applicant's amendments to the claims and explanation of the claimed methods and the use of the terminology in these methods.

Art Unit: 1647

7. Claim Rejections - 35 USC § 103

A. Claims 1-10 remain rejected under 35 USC 103 and claims 11-20 and new claims 27-30 are also rejected for the reasons already of record on pages 9-12 of the Office Action dated 5/8/02. Applicant argues that the present invention provides the first real time in vivo evidence of GPCR oligomerization in intact cells and that until the present invention, accurate, meaningful in vivo data was not possible. Applicants further argue that the teachings of White et al. are based on in vitro results and, therefore, there is no evidence of any actual oligomerization of these GPCRs. Applicant also argues that Miyawaki et al. do not teach that GPCRs can be used in FRET experiments and that efficient expression of these fusion proteins may not be possible. Finally, the Applicant argues that Hebert et al. merely suggest the use of FRET to demonstrate that GPCRs form biologically regulated dimers in whole cells, but did not actually obtain any data to that effect.

These arguments have been considered, but are not deemed persuasive. Even though the Applicants may be the first to demonstrate accurate, real-time in vivo data demonstrating that GPCR oligomerize, this concept, respectfully, is not unobvious over the prior art. The prior art does teach that GPCRs are believed to form oligomers (White et al.) and the prior art does teach that proteins which are believed to form oligomers can be labeled with fluorescent donors and acceptors (Miyawaki et al.). The methods for producing fluorescently labeled fusion proteins of GPCRs would be identical to that for producing these fusion proteins of non-GPCRs. In other words, the recombinant techniques and expectation of success are the same. Therefore, there would have been a reasonable expectation of success for one of ordinary skill in the art at the time of the present invention to have combined the teachings of Miyawaki et al. and White et al. to produce fluorescently labeled GPCR fusion proteins for transfection into cell lines. Furthermore, the artisan would have had a reasonable expectation of success in expressing these fusion proteins on the cell surface in absence of evidence to the contrary. Respectfully, Applicant has not provided any unexpected results by expressing functional GPCR-fluorescent fusion proteins on the surface of the cell. Therefore, even though Hebert et al. only suggested that real-time in vivo FRET analysis of GPCRs would be a logical next step in order to determine in vivo oligomerization of FRET receptors, this reference, in view of White et al. and Miyawaki et al. would render the present invention obvious.

Art Unit: 1647

B. Claims 5 and 10 remain rejected under 35 USC 103 and new claims 27-30 are also rejected for the reasons already of record on pages 12-14 of the Office Action dated 5/8/02. Applicant's arguments and the Examiner's rebuttal are recited in paragraph A of this rejection. Applicants further argue that the GFP fusion proteins of Gama et al. do not provide any indication as to how these fluorescent fusion proteins can be utilized in a FRET assay, nor that this interaction between proteins can be measured. These arguments have been considered, but are not deemed persuasive. The Gama et al. reference was not cited by the Examiner to show how these truncation mutants can be used in a FRET assay, but that it would have been obvious to produce truncated GPCR for a number of reasons which do not include their use in FRET assay. As recited on page 12 of the Office Action dated 5/8/02, truncation mutants provide valuable information on the structure-function relationship of a protein. By altering or deleting certain amino acids of a protein, one can better understand protein function. Furthermore, the claims do not recite that the truncated GPCRs are in any way involved in the FRET assay, only that the GPCRs are truncated. Therefore, regardless of the assay, it would have been obvious to the artisan at the time of the invention to have truncated a GPCR to perform these structure-function studies. Regarding the FRET assay, it would have been obvious to the artisan to have produced truncation mutants to determine which amino acid residues of the GPCRs were involved in oligomerization. Therefore, the teachings of Gama et al. coupled with the teachings of White et al., Miyawaki et al. and Hebert et al. render the present invention obvious.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
January 13, 2003

